IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9463

Bartle, J. April 6, 2016

Dana G. Ellis ("Ms. Ellis"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the Show Cause process, we must determine whether Ms. Ellis has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Rick Ellis, the spouse of Ms. Ellis, has also submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the claimant's attorney must complete Part III if the claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a. & I.22.

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describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for sixty-one days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for sixty days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49.

In April 2013, Ms. Ellis submitted a completed Green Form to the Trust signed by her attesting physician, Robert L. Rosenthal, M.D. ("Dr. Rosenthal"). Based on an echocardiogram dated March 26, 2009,[5] Dr. Rosenthal attested in Part II of the Green Form that Ms. Ellis suffered from congenital aortic valve abnormalities and aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation.[6] Dr. Rosenthal further attested that Ms. Ellis had undergone surgery to repair or replace her aortic and/or mitral valve(s) following the use of Pondimin® or Redux™.[7] Based on these findings, Ms. Ellis would be entitled to Matrix B-1, Level III benefits in the amount of $178,867.[8]

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5. Because the March 26, 2009 echocardiogram was performed after the end of the Screening Period, Ms. Ellis relied on an echocardiogram dated April 4, 2002 to establish her eligibility to receive Matrix Benefits.

6. Under the Settlement Agreement, the presence of congenital aortic valve abnormalities or aortic stenosis with an aortic valve area of less than 1.0 square centimeter by the Continuity Equation requires the payment of reduced Matrix Benefits for a claim based on damage to the aortic valve. See Settlement Agreement §§ IV.B.2.d.(2)(c)i)a) & IV.B.2.d.(2)(c)i)e).

7. Dr. Rosenthal also attested that Ms. Ellis suffered from mild mitral regurgitation and New York Association Functional Class II symptoms. These conditions are not at issue in this claim.

8. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c(3)(a).

In the report of the April 4, 2002 echocardiogram of Ms. Ellis,[9] the reviewing cardiologist, Richard Lane, M.D. ("Dr. Lane"), stated, "Mild aortic insufficiency by color." Dr. Lane, however, did not specify a percentage as to claimant's level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent of the left ventricular outflow tract height. Settlement Agreement § I.22.

In August, 2013, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E. ("Dr. Wang"), one of its auditing cardiologists. In audit, Dr. Wang determined that there was no reasonable medical basis for finding that Ms. Ellis had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Wang explained, "There was no evidence of aortic regurgitation based on the studies performed on 5/31/02 and 3/26/09."

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9. The attesting physician relied on the report of the April 4, 2002 echocardiogram because Ms. Ellis was unable to obtain a copy of the echocardiogram tape. See Settlement Agreement § VI.C.2.f. The Trust did not contest that Ms. Ellis had submitted the affidavit required to rely on an echocardiogram no longer in existence.

Based on Dr. Wang's finding, the Trust issued a post-audit determination denying the claim of Ms. Ellis. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. Ellis contested this adverse determination.[10] In contest, Ms. Ellis argued that the auditing cardiologist failed properly to "consider the evidence that was favorable to the Claimant," namely, the report of her April 4, 2002 echocardiogram. Ms. Ellis also asserted that the absence of aortic regurgitation on the May 31, 2002 and March 26, 2009 echocardiograms does not support the conclusion that her April 4, 2002 echocardiogram also did not show aortic regurgitation. She maintains "there are many factors that can account for a change in the [aortic insufficiency] level." In addition, she argued that she may establish an FDA Positive[11]

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10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

11. Only one of the Settlement Agreement's two definitions of "FDA Positive" applies to this claim: "With respect to a diagnosis based on an Echocardiogram conducted after September 30, 1999, FDA Positive is defined as mild or greater regurgitation of the aortic valve of the heart and/or moderate or greater regurgitation of the mitral valve of the heart as these levels are defined in Singh (1999) and measured by an echocardiographic examination performed and evaluated by qualified medical personnel following the protocol as outlined in Feigenbaum (1994) or Weyman (1994)." Settlement Agreement

diagnosis pursuant to §§ VI.C.2.f. and VI.C.4.a.(8) of the Settlement Agreement by submitting a Gray Form and either a copy of the supporting echocardiogram or an affidavit if the supporting echocardiogram is no longer in existence. According to Ms. Ellis, however, these provisions of the Settlement Agreement do not allow the Trust to consider other evidence to determine her eligibility for (as contrasted with entitlement to) Matrix Benefits.[12]

In support of her arguments, Ms. Ellis submitted a declaration of Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. ("Dr. Dlabal"), who stated in pertinent part:

> 3. Again, the study is technically very poor with considerable artifact on all frames.
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> 4. The [parasternal long-axis] view has no interpretable or diagnostic aortic valve Doppler signal. Between 1:45 and 1:50 there is a splotchy Doppler signal, Nyquist level not visible, showing a small blue jet, mixed within larger red outflow jets, not diagnostic of anything. (If anything, though, there is mild [aortic insufficiency].)
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> 5. The Apical [two-chamber] and [3-chamber] views have considerable Doppler signal, which is again uninterpretable. Between 11:18-11:25, there is an LVOT Doppler

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§ I.22.b (footnotes omitted).

12. Ms. Ellis also argued that the Trust could not rely on the May 31, 2002 echocardiogram because it was not evaluable and that the Trust could not rely on the March 26, 2009 echocardiogram because it was not relevant.

> jet, Nyquist level not visible (looks like 51 or 61), without diagnostic evidence of [aortic insufficiency]. (Again, if anything, one would lean toward the presence of mild [aortic insufficiency], but not technically adequate for diagnostic purposes.)
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> 6. Since one cannot rely on the study to prove [aortic insufficiency], it is also not reasonable to rely on it to disprove [aortic insufficiency]. All that can accurately be said is that it is non-diagnostic as to the presence or absence of [aortic insufficiency].
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> 7. The treating doctor's finding of mild [aortic insufficiency] on 4/4/02 indicates that the patient, in reasonable medical certainty, also had mild [aortic insufficiency] on 5/31/02. However, if the patient had no [aortic insufficiency] on 5/31/02 and again on 3/26/09, there are several factors that could account for any decrease in the level of [aortic insufficiency] from the prior study, including but not limited to: a change in severity of inflammation of the aortic leaflets, a progression toward stenosis as the dominant lesion, a change in the systemic afterload (arterial resistance to flow), or a combination of all three factors.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration in which she again concluded that there was no reasonable medical basis for finding that Ms. Ellis had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Wang stated in relevant part:

> 10. Based on my review, I confirm my finding at audit that there is no reasonable

> medical basis to conclude that Claimant had mild aortic regurgitation in between commencement of Diet Drug use and the close of the Screening Period. The April 2, 2002 Eligibility Echocardiogram was destroyed and was therefore not available for review either at audit or at contest. I reviewed the report of the April 2, 2002 study, and the declaration of Dr. Richard Lane, as well as the available studies, dated May 31, 2002 and March 26, 2009. Both the May 31, 2002 and March 26, 2009 studies were evaluable. Aortic regurgitation was not present on either study. There is no reason to conclude that aortic regurgitation would have been seen on April 4, 2002.
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> 11. I disagree with Dr. Dlabal's assertion that "a change in severity of inflammation of the aortic leaflets, a progression towards stenosis as the dominant lesion, a change in the systemic afterload . . . or a combination of all three factors" might have led to a decrease in aortic regurgitation from the time of the 4/4/02 study until the time of the 5/31/02 and 3/26/09 studies were performed. I have reviewed at least 500 [echocardiograms] of aortic stenosis and have performed at least 300 [transesophageal echocardiograms] for transcatheter aortic valve replacement. The level of aortic regurgitation may decrease while the valve gets more stenotic, but aortic regurgitation does not disappear completely.

The Trust then issued a final post-audit determination, again denying the claim. Ms. Ellis disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See

Settlement Agreement § VI.E.7; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why her claim should be paid. On June 29, 2015, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 9422 (June 29, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Ms. Ellis then served a response upon the Special Master. The Trust submitted a reply on September 3, 2015, and Ms. Ellis submitted a sur-reply on September 18, 2015. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[13] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C. ("Dr. Abramson"), to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See Audit Rule 35.

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13. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. See id.

The issue presented for resolution of this claim is whether Ms. Ellis has met her burden of proving that there is a reasonable medical basis for finding that she suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See Audit Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See Audit Rule 38(b).

In support of her claim, Ms. Ellis reasserts the arguments made in contest. In particular, she argues that she has satisfied the eligibility requirements of the Settlement Agreement because: (1) she was diagnosed as FDA Positive based on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period; (2) she submitted the results of that echocardiogram, which was performed by a qualified physician, on a Gray Form as required by the Settlement Agreement; and (3) she submitted the required affidavit to establish that the echocardiogram that forms the basis of her eligibility was no longer in existence. According to Ms. Ellis, once a claimant submits the necessary information as to

eligibility, entitlement to Matrix Benefits is "automatic" and the Settlement Agreement precludes consideration of any information or even an audit as to the medical condition that forms the basis of the claim of eligibility for Matrix Benefits. She contends that if the parties wanted eligibility and entitlement to Matrix Benefits to be reviewed in the same way, they would have written that requirement into the Settlement Agreement. Finally, in support of her claim, Ms. Ellis submits a supplemental declaration from Dr. Dlabal, stating in relevant part:

> 3. With regard to Dr. Wang's declaration, I see no reason to dispute the treating cardiologist's finding of mild [aortic insufficiency] on 4/4/02. The report is consistent with toxic exposure to the diet drugs and the time course following exposure, as well as disease expression in the form of aortic leaflet inflammation.
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> 4. The echocardiogram dated 5/31/02, while technically poor, does show "recognizable [aortic insufficiency]." It was simply too poor to quantitate the [aortic insufficiency] as trace, mild or worse. The fact that it is "nondiagnostic" for evaluation of severity of [aortic insufficiency] does not exclude the presence of "some" [aortic insufficiency]. (See my declaration dated 12/16/13.)
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> 5. The later echocardiogram dated 3/26/09 is reported in a format where the video clips last no more than 1-2 beats, especially the all-important Doppler clips, which are obtained at Nyquist = 0.48. This makes interpretation of anything very difficult, but especially small amounts of [aortic insufficiency]. Nevertheless, we can

convince ourselves of the presence of "some" [aortic insufficiency] as follows:

Loop 4, splotchy Doppler, [parasternal long-axis] "suggests" [aortic insufficiency].
Loop 19, [apical four-chamber], splotchy Doppler "suggests" faint [aortic insufficiency].
Loop 29, [apical two-chamber] splotchy Doppler shows "some" [aortic insufficiency].
Loop 37, [apical five-chamber], splotchy Doppler shows "some" [aortic insufficiency] in late diastole.

6. In addition, circumstantial support for [aortic insufficiency] appears on the following:

Images 22, 30, and 32 which are [continuous-wave] Doppler recordings of aortic flow and appear to be well separated from mitral flow. These consistently show an [aortic insufficiency] signal in diastole, again not sufficiently clear to quantitate, but clearly and consistently present.

7. In my opinion, based on a reasonable medical certainty, the patient began with mild [aortic insufficiency] on 4/4/02 and continued to exhibit some [aortic insufficiency] throughout her course, technical quality of the images notwithstanding. That [aortic insufficiency] should have lessened over time is consistent with and medically reasonable based upon the factors previously cited, including change in valve inflammation which must have happened over the years, a progression to aortic stenosis as the dominant lesion which did happen, and a change in afterload due to internal autonomic adjustment and/or medications.

8. Thus, Dr. Wang was correct when she stated that the level of [aortic insufficiency] may decrease while the valve becomes more stenotic. However, she was incorrect when she believed that the mild

> [aortic insufficiency], which was diagnosed by the treating cardiologist on 4/4/02, had ever disappeared completely in this case.

In response, the Trust argues that Ms. Ellis has not established a reasonable medical basis for a finding that she had mild aortic regurgitation. The Trust also asserts that the Settlement Agreement and our prior decisions permit it to rely on other echocardiographic studies in determining whether there is a reasonable medical basis for an attesting physician's finding of the requisite level of regurgitation on an echocardiogram used to establish a claimant's eligibility. Finally, the Trust points out that, while Ms. Ellis contends that the Trust ignored evidence in support of her claim, she essentially asks the Trust to exclude her May 31, 2002 echocardiogram.

The Technical Advisor, Dr. Abramson, reviewed the claim and concluded that there was no reasonable medical basis for finding that Ms. Ellis had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Specifically, Dr. Abramson explained, in pertinent part:

> I reviewed the May 31, 2002 and 2009 echocardiograms of this Claimant. Both studies are of good quality. There is no aortic regurgitation in any view on either study by color flow, pulsed-wave or continuous-wave Doppler. The 2009 study demonstrated severe aortic stenosis.
>
> Regarding Dr. Dlabal's comments about this study being non-diagnostic for aortic

> regurgitation, I can say with a high degree of confidence that there was no aortic regurgitation on either study. The absence of aortic regurgitation does not make it non-diagnostic for aortic regurgitation; it is diagnostic for no aortic regurgitation.
>
> The real issue in this case is if it is possible to have mild aortic regurgitation on an echocardiogram in April 2002, which completely disappears two months later and remains absent seven years later. Aortic regurgitant lesions do not disappear. The normal progression for them is to stabilize or worsen. They can vary slightly from day to day based on hemodynamics such as blood pressure, blood volume, or medications, but they will not disappear completely.
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> Based on the May 31, 2002 and March 26, 2009 echocardiograms, which demonstrate no aortic regurgitation, it is highly unlikely that there was any aortic regurgitation on the April 2002 study. Accordingly, there is no reasonable medical basis to conclude that Claimant's April 4, 2002 echocardiogram reveals the presence of at least mild aortic regurgitation.

In response to the Technical Advisor Report, Ms. Ellis argues that Dr. Abramson engaged in "junk science," "guess-work," and "speculation" as to claimant's April 4, 2002 echocardiogram. Ms. Ellis also submits that the Technical Advisor Report should be disregarded because it was "non-substantive" and "baseless." In addition, Ms. Ellis contends that the auditing cardiologist and the Technical Advisor relied on their own subjective findings. Ms. Ellis further argues that the opinions of the reviewing cardiologist and the attesting physician are entitled

to deference. Finally, Ms. Ellis notes that the Settlement Agreement does not require the level of regurgitation to remain constant over time.

After reviewing the entire Show Cause Record, we find the arguments of Ms. Ellis to be without merit. As an initial matter, she does not adequately refute the specific conclusions of the auditing cardiologist and the Technical Advisor that the March 26, 2009 echocardiogram does not reveal the presence of at least mild aortic regurgitation. Despite the opinion offered by Ms. Ellis' expert, Dr. Dlabal, that the March 26, 2009 echocardiogram was uninterpretable, the reviewing cardiologist, the auditing cardiologist, and the Technical Advisor each concluded that claimant's May 31, 2002 echocardiogram was "evaluable." Moreover, the auditing cardiologist and the Technical Advisor determined that the study did not demonstrate any aortic regurgitation.[14]

Ms. Ellis argues that the Trust cannot rely on her May 31, 2002 and March 26, 2009 echocardiograms in determining whether there was a reasonable medical basis for her attesting physician's representation of mild aortic regurgitation based on

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14. The detailed review by both the auditing cardiologist and the Technical Advisor undermine the assertions made by Ms. Ellis that the auditing cardiologist substituted her subjective opinion in lieu of applying the reasonable medical basis standard, that Dr. Abramson "failed to review the cardiologists' qualified opinions," and that Dr. Abramson's report and conclusions were "non-substantive" and "baseless."

the report of her April 4, 2002 echocardiogram. In support of this argument, Ms. Ellis relies on the following provisions of the Settlement Agreement:

> B. **COMPENSATION BENEFITS PAYABLE FROM FUND B**
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> 1. **ELIGIBLE CLASS MEMBERS.** The following Class Members, and only such Class Members, shall be entitled to the compensation benefits from Fund B ("Matrix Compensation Benefits"):
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> a. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by Date 2;
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> . . . .
>
> 2. **BENEFITS AVAILABLE**
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> . . . .
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> h. Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive (but not also as having Mild Mitral Regurgitation) by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and have registered for settlement benefits by Date 2, ... shall be eligible for Matrix payments for Matrix-Level Conditions resulting from the valve or valves for which there was an FDA Positive

> diagnosis by a Qualified Physician by the end of the Screening Period, subject to the above provision that if he/she qualifies for more than one benefit, he/she shall be entitled to the higher benefit, but not both.

Settlement Agreement §§ IV.B.1.a & IV.B.2.h.

Ms. Ellis' reliance on §§ IV.B.1.a and IV.B.2.h of the Settlement Agreement is misplaced. Contrary to her argument, compliance with these provisions does not result in an "automatic" entitlement to Matrix Benefits. This is particularly true where, as here, another echocardiogram conducted during the Screening Period (and less than two months after the echocardiogram on which the claimant relies) reflects that the claimant did not have the required level of aortic regurgitation to be eligible for Matrix Benefits. Indeed, the argument advanced by Ms. Ellis ignores § VI.C.4.b of the Settlement Agreement, which provides that:

> If the Class Member seeking a Matrix payment is unable to obtain the [Medical Information] described above through the exercise of reasonable efforts, the Trustees and/or Claims Administrator(s) shall have the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty to support the claim that the Class Member's condition entitles him or her to a Matrix payment, subject to review by the Court as set forth in Section VIII.D. If this evidence establishes the Class Member's

> condition to the satisfaction of the Trustees and/or Claims Administrator(s), the Class Member shall be entitled to receive the appropriate Matrix Compensation Benefits.

Thus, contrary to the argument of Ms. Ellis, the Settlement Agreement does not require the Trust to consider only documents that support payment of a claim. Under the plain text of § VI.C.4.b, the Trust may "consider" other material and a claimant is only entitled to receive "appropriate" Matrix Benefits if the materials establish the necessary medical condition "to the satisfaction of the Trustees and/or Claims Administrator(s)." Ms. Ellis is correct in noting that the Settlement Agreement, upon the satisfaction of certain conditions, allows a claimant to rely on the results of an echocardiogram when the echocardiogram itself can no longer be located. See id. §§ VI.C.2.e, VI.C.2.f. However, nothing in the Settlement Agreement requires the Trust simply to accept the findings stated in an echocardiogram report where the echocardiogram tape is no longer in existence.

Further, Ms. Ellis' argument ignores § VI.E.6 of the Settlement Agreement, which states:

> In conducting an audit of those Claims and Requests for Credit selected for audit, the Trustees and/or Claims Administrator(s) shall follow the following procedure: All Accelerated Implementation Option acceptance form(s) ("PINK FORM"), registration form(s) ("BLUE FORM"), videotapes or disks of Echocardiograms, medical reports, and other information submitted by AHP in support of a

> Request for Credit or by a Class Member in support of a Claim, together with a copy of the claimant's medical records, and Echocardiogram videotapes or disks obtained by the Trustees/Claims Administrator(s) shall be forwarded to a highly-qualified, independent, Board-Certified Cardiologist (hereinafter referred to as the "Auditing Cardiologist") selected by the Trustees/ Claims Administrator(s). After thoroughly reviewing these materials, the Auditing Cardiologist shall make a determination as to whether or not there was a reasonable medical basis for the representations made by any physician in support of the Claim or Request for Credit.

Id. § VI.E.6; see also Audit Rule 7(a). Accepting the interpretation endorsed by Ms. Ellis would effectively negate this provision of the Settlement Agreement.

The interpretation that Ms. Ellis urges us to adopt is also not supported by the parties responsible for drafting the Settlement Agreement, namely, Class Counsel and Wyeth. In October 2010, we requested the views of Wyeth and Class Counsel as to the parties' intention with respect to §§ VI.C.2.e, VI.C.2.f, and VI.C.4.b of the Settlement Agreement. See PTO No. 8549 (Oct. 18, 2010). In a joint response, Class Counsel and Wyeth stated their position as follows:

> Where the tape or disk of the Qualifying Echocardiogram, the echocardiogram that supports the presence of a Matrix Level condition and/or the echocardiogram that supports the presence or absence of a Reduction Factor no longer exists or cannot be found, the Class Member must submit a sworn affidavit from the last custodian of the tape or disk documenting that such tape

> or disk no longer exists and explaining to the satisfaction of the Trust the circumstances under which the tape or disk "came to be misplaced or destroyed."
>
> If the Class Member makes that showing, the Trust may rely upon other medical evidence regarding the presence or absence of the regurgitation diagnosed by the Qualifying Echocardiogram, the presence or absence of a Matrix Level condition, and the presence or absence of a Reduction Factor, including the written [echocardiogram] report of the missing tape or disk prepared when the echocardiogram was conducted and all other Medical Information submitted on the claim, such as hospital records, results of cardiac catheterizations, surgical reports, pathology reports, and any other echocardiogram studies. The Auditing Cardiologist shall weigh all such Medical Information and the totality of the medical facts presented in evaluating whether there is a reasonable medical basis for the level of regurgitation on the Qualifying Echocardiogram, the presence of a Matrix Level condition and the absence of pertinent reduction factors as asserted by the Attesting Physician in the Green Form submitted by the Class Member in support of the Class Member's Matrix claim.

(Emphasis added.)

This is precisely what occurred here. While Ms. Ellis was permitted to proceed with her claim upon submission of the required documentation to establish that her April 4, 2002 echocardiogram was no longer in existence, the Trust was permitted to consider, among other things, her May 31, 2002 and March 26, 2009 echocardiograms in determining whether there was a reasonable medical basis for finding that she had mild aortic regurgitation on the April 4, 2002 eligibility echocardiogram.

As a review of those materials revealed that the attesting physician's representation lacked a reasonable medical basis, the Trust properly denied her request for Level III Matrix Benefits.

Finally, Ms. Ellis is incorrect that her argument is consistent with this court's decision in PTO No. 2662, which mandated a 100 percent audit requirement for all claims for Matrix Benefits. See Mem. in Supp. of PTO No. 2662 at 13 (Nov. 26, 2002). To the contrary, adopting the position of Ms. Ellis would be inconsistent with this court's decision, as well as with § VI.E of the Settlement Agreement, which governs the audit of claims for Matrix Benefits. Thus, the Settlement Agreement's provisions, taken together, do not support the conclusion that merely submitting an echocardiogram report that facially satisfies the Settlement Agreement's eligibility provisions automatically results in an entitlement to Matrix Benefits. Accordingly, we decline the request of Ms. Ellis to interpret the Settlement Agreement in this fashion.[15]

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15. The result sought by Ms. Ellis is particularly inappropriate where, as here, a claimant seeks to establish eligibility based on a missing echocardiogram and, at the same time, requests the court to ignore an existing echocardiogram conducted during the Screening Period that reveals that the claimant did not have the requisite level of aortic regurgitation to satisfy the Settlement Agreement's eligibility requirements. The Settlement Agreement's provision allowing a claimant to proceed, in certain circumstances, even in the face of a missing echocardiogram was designed to ensure that claimants who, through no fault of their own, did not have an echocardiogram that could be reviewed by the Trust would still be able to proceed with a request for Matrix Benefits. It was not designed to favor such claimants at the

For the foregoing reasons, we conclude that Ms. Ellis has not met her burden of proving that there is a reasonable medical basis for finding that she had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of the claim of Ms. Ellis for Matrix B-1, Level III benefits and the related derivative claim submitted by her spouse.

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expense of those claimants who had echocardiograms which could be reviewed by the Trust's auditing cardiologists.